

**Notice of Allowability**

Application No.

10/696,282

Applicant(s)

WILSON ET AL.

Examiner

David Guzo

Art Unit

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 10/26/05.
2. ☒ The allowed claim(s) is/are 3, 10 and 12.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 01/23/06, 2/24/06, 4/27/06, 7/20/06, 9/10/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 1/4/06
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Cathy A. Kodroff on 1/4/06.

The application has been amended as follows:

In the **Specification**:

On Page 4, replace lines 18-19 in their entirety with:

--Fig. 2 illustrates the predicted secondary structure of AAV-1 ITR ~~[nt 1—146 of SEQ ID NO:1]~~ (nt 1 – 146 of SEQ ID NO:1). The nucleotides in AAV-2 ~~[nt 1—144 of SEQ ID NO:18]~~ (nt 1 –144 of SEQ ID NO:18) and AAV-6 ~~[nt 1—136 of SEQ ID NO:19]~~ (nt 1 – 136 of SEQ ID NO:19) are shown in italic and bold respectively.--

On Page 4, replace lines 24-26 in their entirety with:

--Fig. 3B is a detailed illustration of a 71 bp homologous region among AAV-1 ~~[438-531 of SEQ ID NO:1]~~ (438-531 of SEQ ID NO:1), AAV-2 ~~[424-513 of SEQ ID NO:18]~~ (424-513 of SEQ ID NO:18) and AAV-6 ~~[423-512 of SEQ ID NO:19]~~ (423-512 of SEQ ID NO:19). Nucleotides that differ among those are indicated by arrows.--

In the **Claims**:

In Claim 3 line 5, delete "335 to 2304" and substitute --334 to 2306--. On line 6, delete "335" and substitute --334--.

The above amendment to the specification was necessary because the amendment to the specification filed 10/26/05 did not comply with 37 CFR 1.121. Neither underlining nor double bracketing was used to show text added to the specification. The examiner has reiterated applicants' amendment using underlining and cross-through to show the text added and deleted, respectively.

The amendment to claim 3 is necessary to render the nucleotide positions of the rep 78 and rep 68 within SEQ ID NO:1 consistent with the positions recited in the specification.

A provisional obviousness type double patenting rejection of instant claims 3, 10 and 12 over at least claims 1, 9, 12 and 17 of co-pending application 10/696,900 is warranted. Both sets of claims read on the same nucleotide sequences and host cells containing said sequences. However, since said provisional obviousness type double patenting rejection would be the only rejection, said rejection is withdrawn and the instant case passed to issue. A provisional obviousness type double patenting rejection will be made in the co-pending application and said provisional rejection will become a regular obviousness type double patenting rejection when the instant case issues.

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The instantly claimed AAV rep and cap sequences are free of the art. While the prior art is replete with disclosures of AAV rep and cap genes used as helper sequences for the packaging of recombinant AAV vectors (See for example, Natsoulis et al., US 6,027,931), said references do not teach the specifically claimed rep and cap sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
January 9, 2006

  
DAVID GUZO  
PRIMARY EXAMINER